Remarks

Claims 1-22 are pending. Claim 1 has been amended. Support for this amendment can be found in paragraph [0009] of the specification. No new matter is added by this amendment.

Response to Restriction Requirement

The Office Action requires restriction to one of the following four groups of claims:

Group I: Claims 1-14, drawn to dermal application system;

Group II: Claims 15-18, drawn to an application system comprising mixtures of different ALA derivatives;

Group III: Claims 19-20, drawn to method for preparation of the application system; and

Group IV: Claims 21-22, drawn to use of application system;

As required in response to the Restriction Requirement, Applicants provisionally elect Group I (claims 1-14) with traverse.

The Office Action further requires election of a species from among the following:

(1) ALA derivative as a compound of general formula $R^2{}_2N\text{-}CH_2COCH_2COOR^1$.

(2) A species of polymer to which the claims shall be restricted if no generic claim is finally held to be allowable.

As required in response to the Species Requirement, Applicants provisionally elect with traverse the species (1) 5-aminolevulinic acid methyl ester, i.e., wherein R^1 is methyl group and each of R^2 are hydrogen atoms, and (2) polymer-acrylates. The Office Action notes that claims 1-22 are generic and that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as set forth in 37 CFR §1.141.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The Examiner proposes that the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. PCT Rule 13.2 states:

> ... the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, the Examiner rejects unity of invention based on the assertion that the common technical feature is allegedly shown in the prior art. Specifically, the Examiner assert that the common technical feature in all of the groups is ALA derivative, which is allegedly disclosed in WO 96/06602. This is incorrect.

Claim 1 is directed to a dermal application system containing an ALA derivative, "wherein the crystals of the ALA derivative have a size of less than approximately 200 μm." Thus, the common technical feature uniting the claims is crystal ALA derivative of a size less than 200 μm. As discussed in paragraphs [0004] to [0008], this size limitation solves the problems of stability and low release speeds for ALA dermal application compositions in the art.

Applicants respectfully point out that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature (i.e., dermal application system having crystal ALA derivative of a size less than 200 μm) and thereby destroy the single inventive concept. Thus, the Examiner has not met the burden for establishing a lack of unity of invention and the restriction is improper.

Applicants also traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. Applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. Accordingly, for this additional reason, there is no basis for maintaining the restriction requirement.

Favorable consideration of claims 1-22 is earnestly solicited.

A Credit Card Payment authorizing payment in the amount of $120.00, representing the fee for a large entity under 37 C.F.R. § 1.17(a)(1) for a One Month Extension of Time, and a

Request for Extension of Time are hereby enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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